

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305
	Filing Date		2000-10-06
	First Named Inventor		
	Art Unit		1637
	Examiner Name		
	Attorney Docket Number		FORS-04447

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4511502		1985-04-16		Whole Document
	2	4511503		1985-04-16		Whole Document
	3	4512922		1985-04-23		Whole Document
	4	4518526		1985-05-21		Whole Document
	5	4683194		1987-07-28		Whole Document
	6	4683195		1987-07-28		Whole Document
	7	4683202		1987-07-28		Whole Document
	8	4775619		1988-10-04		Whole Document

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305	
	Filing Date		2000-10-06	
	First Named Inventor			
	Art Unit		1637	
	Examiner Name			
	Attorney Docket Number		FORS-04447	

	9	4876187		1989-10-24		Whole Document
	10	5011769		1991-04-30		Whole Document
	11	5108892		1992-04-28		Whole Document
	12	5118605		1992-06-02		Whole Document
	13	5144019		1992-09-01		Whole Document
	14	5210015		1993-05-11		Whole Document
	15	5380833		1995-06-10		Whole Document
	16	5403711		1995-04-04		Whole Document
	17	5422253		1995-06-06		Whole Document
	18	5427930		1995-06-27		Whole Document
	19	5487972		1996-01-30		Whole Document

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305
	Filing Date		2000-10-06
	First Named Inventor		
	Art Unit	1637	
	Examiner Name		
	Attorney Docket Number	FORS-04447	

	20	5494810		1996-02-27		Whole Document
	21	5541311		1996-07-30		Whole Document
	22	5545729		1996-08-13		Whole Document
	23	5698400		1997-12-16		Whole Document
	24	5719056		1998-02-17		Whole Document
	25	5783392		1998-07-21		Whole Document
	26	5792614		1998-08-11		Whole Document
	27	5830664		1998-11-03		Whole Document
	28	5843654		1998-12-01		Whole Document
	29	5843669		1998-12-01		Whole Document
	30	5874283		1999-02-23		Whole Document

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305	
	Filing Date		2000-10-06	
	First Named Inventor			
	Art Unit		1637	
	Examiner Name			
	Attorney Docket Number		FORS-04447	

	31	5882867		1999-03-16		Whole Document
	32	5888780		1999-03-30		Whole Document
	33	5985557		1999-11-16		Whole Document
	34	5994069		1999-11-30		Whole Document
	35	6372424		2002-04-16		Whole Document

If you wish to add additional U.S. Patent citation information please click the Add button.

#### U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

#### FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2i</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	EP0411186	EP		1991-02-06		Whole Document	<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305	
	Filing Date		2000-10-06	
	First Named Inventor			
	Art Unit		1637	
	Examiner Name			
	Attorney Docket Number		FORS-04447	

	2	EP0482714	EP		1991-10-22		Whole Document	<input type="checkbox"/>
--	---	-----------	----	--	------------	--	----------------	--------------------------

If you wish to add additional Foreign Patent Document citation information please click the Add button

### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	US Patent Application No.: 08/337,164, Filed: 1994-11-03, Dahlberg	<input type="checkbox"/>
	2	US Patent Application No.: 08/402,601, Filed: 1995-03-09, Dahlberg	<input type="checkbox"/>
	3	Abramson, et al. "Characterization of the 5'-3' Exonuclease Activity of Thermus Aquaticus DNA Polymerase," FASEB J. 5(4) 386 (1991)	<input type="checkbox"/>
	4	Akhmetzjanov, et al. "Molecular cloning and nucleotide sequence of the DNA polymerase gene from Thermus flavus," Nucl. Acids Res. 20:5839 (1992)	<input type="checkbox"/>
	5	Altamirano, et al., "Identification of Hepatitis C Virus Genotypes among Hospitalized Patients in British Columbia, Canada," J. Infect. Dis. 171:1034-1038 (1995).	<input type="checkbox"/>
	6	Anderson, et al. "Quantitative Filter Hybridization", in Nucleic Acid Hybridization, Eds Hames & Higgins, IRL Press, Washington, DC, pp. 73-111 (1985)	<input type="checkbox"/>
	7	Andrews, Electrophoresis, 2nd Edition, ed. Anthony T. Andrews, Clarendon Press, New York, New York (1986), pp. 153-154	<input type="checkbox"/>
	8	Antao, et al. "A thermodynamic study of unusually stable RNA and DNA hairpins," Nucl. Acids Res. 19:5901-5905 (1991)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09684305
Filing Date	2000-10-06
First Named Inventor	
Art Unit	1637
Examiner Name	
Attorney Docket Number	FORS-04447

9	Bambara, et al., "Enzymes and Reactions at the Eukaryotic DNA Replication Fork," J. Biol. Chem. 272:4647-4650 (1997)	<input type="checkbox"/>
10	Barany "The Ligase Chain Reaction in a PCR World," PCR Methods and Applic., 1:5-16 (1991)	<input type="checkbox"/>
11	Barany, "Genetic disease detection and DNA amplification using cloned thermostable ligase," Proc. Natl. Acad. Sci., 88:189-193 (1991);	<input type="checkbox"/>
12	Bardwell, et al. "Specific Cleavage of Model Recombination and Repair Intermediates by the Yeast Rad1-Rad10 DNA Endonuclease," Science 265:2082-2085 (1994)	<input type="checkbox"/>
13	Barnes, et al. "Mechanism of Tracking and Cleavage of Adduct-damaged DNA Substrates by the Mammalian 5'- to 3'Exonuclease/Endonuclease RAD2 Homologue 1 or Flap Endonuclease 1", J. Biol. Chem. 271:29624-29632 (1996)	<input type="checkbox"/>
14	Bergseid , et al. "A High Fidelity Thermostable DNA Polymerase Isolated from Pyrococcus Furiosus," Strategies 4:34-35 (1991)	<input type="checkbox"/>
15	Bhagwat , et al. "The 5'-Exonuclease Activity of Bacteriophage T4 RNase H is Stimulated by the T4 Gene 32 Single-stranded DNA-binding Protein, but Its Flap Endonuclease Is Inhibited," J. Biol. Chem. 272:28523-28530 (1997);	<input type="checkbox"/>
16	Binghui, et al. "Flap endonuclease homologs in archaebacteria exist as independent proteins" TRENDS IN BIOCHEMICAL SCIENCES, ELSEVIER. HAYWARDS, GB, vol. 23, no. 5, '1 May 1998 (1998-05-01)', pages 171-173	<input type="checkbox"/>
17	Bonch-Osmolovskaya, et al. Microbiology (Engl. Transl. of Mikrobiologiya) 57:78-85 (1988)	<input type="checkbox"/>
18	Borges, et al. "A Survey of the Genome of the Hyperthermophilic Archaeon, Pyrococcus furiosus" (Data Genbank on NLM, U.S. Nat. Lib. of Med.) Genome Science & Technology, 1996, Vol. 1, No. 2, pp. 37-46	<input type="checkbox"/>
19	Boynton, et al. "Cloning, sequencing, and expression of clustered genes encoding 13-hydroxybutyryl-coenzymeA (CoA) dehydrogenase, crotonase, and butyryl-CoA dehydrogenase from clostridium acetobutylicum ATCC 824" Journal of Bacteriology. June 1996, Vol. 178, No. 11, pages 3015-3024	<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305
	Filing Date		2000-10-06
	First Named Inventor		
	Art Unit		1637
	Examiner Name		
	Attorney Docket Number		FORS-04447

	20	Brosius, et al. "Spacing of the -10 and -35 regions in the tac promoter: Effect on its in vivo activity" Journal of Biological Chemistry. 25 March 1985, Vol. 260, No.6, pages 3539-3541	<input type="checkbox"/>
	21	Brow, et al. "Differentiation of Bacterial 16S rRNA Genes and Intergenic Regions and Mycobacterium tuberculosis katG Genes by Structure-Specific Endonuclease Cleavage," J. of Clin. Micro. 34:3129-3137 (1996)	<input type="checkbox"/>
	22	Brutlag, et al., "An Active Fragment of DNA Polymerase Produced By Proteolytic Cleavage," Biochem. Biophys. Res. Commun. 37:982-989 (1969)	<input type="checkbox"/>
	23	Bult, et al. "Complete genome sequence of the methanogenic archaeon, Methanococcus jannaschii" Science 273:1058-1062 (1996)	<input type="checkbox"/>
	24	Carballeira, et al. "Purification of a Thermostable DNA Polymerase from Thermus thermophilus HB8, Useful in the Polymerase Chain Reaction," Biotechniques 9:276-281 (1990)	<input type="checkbox"/>
	25	Carr, et al. "Evolutionary conservation of excision repair in Schizosaccaromyces pombe: evidence for a family of sequences related to the Saccharomyces cerevisiae RAD2 gene" NUCLEIC ACIDS RESEARCH, vol. 21, no. 6, March 1993, p. 1345-9	<input type="checkbox"/>
	26	Ceska, et al. "Structure-specific DNA cleavage by 5' nucleases," TIPS 23 (1998)	<input type="checkbox"/>
	27	Ceska, et al., "A helical arch allowing single-stranded DNA to thread through T5 5'-exonuclease," Nature 382:90-93 (1996)	<input type="checkbox"/>
	28	Chamberlin, et al. "Bacteriophage DNA-Dependent RNA Polymerases" The Enzymes, XV:87-108 (1982)	<input type="checkbox"/>
	29	Copley , et al. "Exonuclease Cycling Assay: An Amplified Assay for the Detection of Specific DNA Sequences," BioTechniques 13:888-891 (1992)	<input type="checkbox"/>
	30	Cuthbert "Hepatitis C: Progress and Problems" Clin. Microbiol. Rev. 7:505-532 (1994)	<input type="checkbox"/>



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305
	Filing Date		2000-10-06
	First Named Inventor		
	Art Unit		1637
	Examiner Name		
	Attorney Docket Number		FORS-04447

	31	DeMott, et al. "Human RAD2 Homolog 1 5'-3'-Exo/Endonuclease Can Efficiently Excise a Displaced DNA Fragment Containing a 5'-Terminal Abasic Lesion by Endonuclease Activity," J. Biol. Chem. 271:30068-30076 (1996)	<input type="checkbox"/>
	32	Donnabella, et al. "Isolation of the Gene for the $\beta$ Subunit of RNA Polymerase from Rifampicin-resistant Mycobacterium tuberculosis and Identification of New Mutations," Am. J. Respir. Dis. 11:639-643 (1994)	<input type="checkbox"/>
	33	Doty, et al. "Strand Separation and Specific Recombination in Deoxyribonucleic Acids: Physical Chemical Studies," Proc. Natl. Acad. Sci. USA 46:461-476 (1960)	<input type="checkbox"/>
	34	Duck, et al. "Probe Amplifier System Based on Chimeric Cycling Oligonucleotides," BioTech., 9:142-147 (1990)	<input type="checkbox"/>
	35	Dunn, et al. "Complete Nucleotide Sequence of Bacteriophage T7 DNA and the Locations of T7 Genetic Elements," J. Mol. Biol. 166:477-535 (1983)	<input type="checkbox"/>
	36	Engelke "Purification of Thermus Aquaticus DNA Polymerase Expressed in Escherichia coli," Anal. Biochem 191:396-400 (1990)	<input type="checkbox"/>
	37	Eom, et al. "Structure of Taq polymerase with DNA at the polymerase active site," Nature 382:278-282 (1996)	<input type="checkbox"/>
	38	Erlich, et al. "Recent Advances in the Polymerase Chain Reaction" Science 252:1643-1651 (1991)	<input type="checkbox"/>
	39	Fahy, et al. "Self-sustained Sequence Replication (3SR): An Isothermal Transcription-based Amplification System Alternative to PCR" PCR Meth. Appl., 1:25-33 (1991)	<input type="checkbox"/>
	40	Garforth, et al. "Structure-specific DNA binding by bacteriophage T5 5'3' exonuclease," Nucleic Acids Res. 25:3801-3807 (1997)	<input type="checkbox"/>
	41	Gelfand, PCR Technology - Principles and Applications for DNA Amplification (H.A. Erlich, Ed.), Stockton Press, New York, p. 19 (1989)	<input type="checkbox"/>



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09684305
	Filing Date		2000-10-06
	First Named Inventor		
	Art Unit		1637
	Examiner Name		
	Attorney Docket Number		FORS-04447

	42	GHOSH et al. "Real time kinetics of restriction endonuclease cleavage monitored by fluorescence resonance energy transfer" 1994 Nucleic Acids Research 22(15):3155-3159	<input type="checkbox"/>
	43	Guatelli, et al. "Isothermal, in vitro amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication," Proc. Natl. Acad. Sci., 87:1874-1878 (1990) with an erratum at Proc. Natl. Acad. Sci., 87:7797 (1990)	<input type="checkbox"/>
	44	Harrington, et al. "DNA Structural Elements Required for FEN-1 Binding," J. Biol. Chem. 270:4503-4508 (1995)	<input type="checkbox"/>
	45	Harrington, et al. "Functional domains within FEN-1 and RAD2 define a family of structure-specific endonucleases: implications for nucleotide excision repair," Genes and Develop. 8:1344-1355 (1994)	<input type="checkbox"/>
	46	Harrington, et al., "The characterization of a mammalian DNA structure-specific endonuclease," EMBO Journ. 13:1235-1246 (1994)	<input type="checkbox"/>
	47	Hiraoka, et al. "Sequence of human FEN-1, a structure specific endonuclease, and chromosomal localization of the gene (FEN1) in mouse and human," Genomics 25:220-225 (1995)	<input type="checkbox"/>
	48	Hiraoka, et al. GenBank Acc#: NP_004102; 1999-05-07	<input type="checkbox"/>
	49	Hirao, et al. "Most compact hairpin-turn structure exerted by a short DNA fragment, d(GCGAAGC) in solution: an extraordinarily stable structure resistant to nucleases and heat," Nuc. Acids Res. 22:576-582 (1994)	<input type="checkbox"/>
	50	Holland, et al. "Detection of specific polymerase chain reaction product by utilizing the 5'-3' exonuclease activity of Thermus aquaticus DNA polymerase" Proc. Natl. Acad. Sci. USA 88:7276-7280 (1991)	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

#### EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09684305	
Filing Date	2000-10-06	
First Named Inventor		
Art Unit	1637	
Examiner Name		
Attorney Docket Number	FORS-04447	

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09684305
Filing Date	2000-10-06
First Named Inventor	
Art Unit	1637
Examiner Name	
Attorney Docket Number	FORS-04447

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Mary Ann D. Brow/	Date (YYYY-MM-DD)	
Name/Print		Registration Number	42363

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.